

2018 Current Fiscal Year Report: Advisory Committee on Blood and Tissue Safety and Availability

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2018

3. Committee or Subcommittee

Advisory Committee on Blood and Tissue Safety and Availability

3b. GSA Committee No.

5147

4. Is this New During Fiscal Year?

No

5. Current Charter

10/09/2016

6. Expected Renewal Date

10/09/2018

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

No

10b. Legislation Pending?

Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority

42 USC 217a, Sec 222, Public Health Service Act

13. Effective Date

10/17/1962

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee National Policy Issue Advisory Board

16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open 1 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 1 Meetings and Dates

Purpose	Start	End
The purpose of this meeting was to define a tolerable infectious disease risk in blood safety from a patient's perspective. It focused on creating ground work for a subsequent substantive discussion at a future ACBTSA.	09/13/2018	09/13/2018

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$2,000.00	\$4,000.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$326,080.00	\$332,276.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$9,670.00	\$11,800.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00

18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$65,000.00	\$65,000.00
18d. Total	\$402,750.00	\$413,076.00
19. Federal Staff Support Years (FTE)	2.00	2.00

20a. How does the Committee accomplish its purpose?

The ACBTSA provides recommendations to the Secretary, through the Assistant Secretary for Health, on blood and tissue safety and availability. To accomplish its mission, the Committee collaborates with external and internal stakeholders. Subject to approval of the Secretary or designee, the Committee establishes subcommittees to obtain assistance for carrying out its mission. The established subcommittees provide information on issues for which additional data is needed for the Committee to develop recommendations that are submitted to the Secretary. The subcommittees discuss and pursue objectives in cooperation with other external and internal stakeholders.

Recommendations developed by the subcommittees are given to the Committee for discussion and consideration for them to be forwarded to the Secretary.

20b. How does the Committee balance its membership?

The Committee consists of 23 voting members appointed by the Secretary. In appointing members, the Secretary shall ensure that the Committee includes a diverse group of patient advocates, scientific and health professionals. The Committee is composed of 14 public members, including the Chair, who are selected from State and local organizations, patient advocacy groups, provider organizations, academic researchers, ethicists, physicians, surgeons, scientists, risk communication experts, consumer advocates, legal organizations, and from among communities of persons who are frequent recipients of blood or blood products or have received cells, tissues or organs. While there is no prescribed formula for distribution of membership, every attempt is made to ensure that there is equal and diverse representation. In addition, the membership includes 9 individuals who are designated to serve as official representative members of the blood, blood product, cell, tissue and organ professional organizations or business sectors.

These members include representatives from the AABB, American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations(AOPO), the Organ Procurement and Transplantation Network (OPTN), one of either the American National Red Cross (ARC) or America's Blood Centers (ABC) on a rotating basis. The Committee composition can include additional representation from either the plasma protein fraction community or a trade organization; a manufacturer of blood, plasma or other tissue/organ test kits; a manufacturer of blood, plasma, or other tissue/organ equipment; and a major hospital organization or major hospital accreditation organization. Where more than one

company produces a specified product or process, representatives from those companies shall rotate on the same schedule as public members. Composition of the Committee membership includes physicians, representatives of the blood and plasma and hospital and medical devices communities, and consumer representatives.

20c. How frequent and relevant are the Committee Meetings?

The Committee meets, at a minimum, one time a year. The Committee will hold additional meetings during the year, depending on the availability of funds and public health requirements. At the Committee meetings, the members receive information from various outside sources and then formulate policy recommendations to be given to the Secretary.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The Advisory Committee on Blood and Tissue Safety and Availability provides advice to the Secretary, through the Assistant Secretary for Health, on a range of policy issues to include: (1) identification of public health issues that affect safety and availability of blood supply and blood products; (2) broad public health, ethical and legal issues related to transfusion and transplantation safety; (3) the implications of various economic factors affecting product cost and supply on safety and availability; and (4) risk communications related to these products. These public health concerns require actions that are inherently governmental, thus requiring the framework of FACA to gather advice.

20e. Why is it necessary to close and/or partially closed committee meetings?

All meetings of the Committee have been and will continue to be open to the public. Since June 2010, all Committee meetings have been webcast.

21. Remarks

Through its collaborative efforts with external and internal stakeholders, the Committee has found that maintaining an adequate supply of safe blood for transfusion is integral to public health and a national priority; and instability in the blood centers threatens to exacerbate existing spot blood shortages, reduce resilience in the face of public health emergencies through elimination of surge capacity, and reduce ability to provide the most appropriate routine and specialty products and services. These findings and others indicate a clear and present need to address the immediate crisis and to manage a longer term paradigm shift to stabilize blood centers in the U.S. and to ensure that the continued safety and availability of the U.S. blood supply meets the public health needs. Please note that the term for all non-HHS ex-officio members ended 9/30/18 and it was determined that HHS can no longer have ex-officio members on this committee.

Designated Federal Officer

James J. Berger Senior Advisor for Blood and Tissue Policy

Committee Members	Start	End	Occupation	Member Designation
Alesescu, Pamela	11/07/2015	11/07/2019	Palliative Care Social Worker	Special Government Employee (SGE) Member
Allen, Larry	11/07/2015	11/07/2019	Consumer Advocate	Special Government Employee (SGE) Member
Barr, Mark	10/01/2015	09/30/2018	Organ Transplant Physician	Ex Officio Member
Basavaraju, Sridhar	06/19/2017	09/30/2020	Physician Scientist	Ex Officio Member
Benjamin, Richard	11/28/2016	11/27/2019	Chief Medical Officer	Representative Member
Blumberg, Emily	06/05/2013	06/05/2019	Director, Transplant Infectious Disease	Special Government Employee (SGE) Member
Brennan, Daniel	11/28/2016	11/27/2019	Director, Transplant Nephrology	Special Government Employee (SGE) Member
Brubaker, Scott	10/01/2016	09/30/2020	Tissue Subject Matter Expert	Ex Officio Member
Corning, Diane	04/01/2014	09/30/2020	Policy subject matter expert	Ex Officio Member
Custer, Brian	06/05/2013	06/05/2019	Associate Director, Senior Investigator	Special Government Employee (SGE) Member
Epstein, Jay	03/01/1997	09/30/2018	Physician Executive	Ex Officio Member
Fredrick, Jacquelyn	08/17/2018	08/16/2021	Former CEO, BloodCenter of WI	Special Government Employee (SGE) Member
Greenwald, Melissa	10/01/2015	09/30/2020	Director, Division of Transplantation	Ex Officio Member
Gustafson, Mary	06/07/2011	06/07/2018	Vice President, Global Regulatory Policy	Representative Member
Josephson, Cassandra	11/07/2015	11/07/2018	Professor, Pathology, Laboratory Medicine & Pediatrics	Special Government Employee (SGE) Member
Katz, Louis	12/06/2016	12/05/2018	Chief Medical Officer	Representative Member
Klein, Harvey	03/01/1997	09/30/2020	Physician Executive	Ex Officio Member
Kotton, Camille	12/06/2011	12/06/2018	Clinical Director, Transplant and Immunocompromised Host Infectious Diseases	Special Government Employee (SGE) Member
Levi, Marilyn	09/30/2018	09/30/2020	Director, Division of Transplantation	Ex Officio Member
London, Alex	11/28/2016	11/27/2018	Director	Special Government Employee (SGE) Member
Macasai, Marian	12/06/2012	12/06/2018	Ophthalmologist	Representative Member
Menitove, Jay	03/01/2010	12/06/2017	Clinical Professor, Pathology and Laboratory Medicine	Special Government Employee (SGE) Member
Quillen, Karen	06/07/2011	06/07/2018	Medical Director	Special Government Employee (SGE) Member
Ratcliff, Nora	10/03/2016	09/30/2018	Physician Subject Matter Expert VA Health	Ex Officio Member
Riedel, Stephan	11/28/2016	11/27/2019	Associate Professor	Representative Member
Simon, Clayton	10/01/2015	09/30/2018	Military Medicine SME	Ex Officio Member
Skinner, Mark	11/07/2015	11/07/2018	President & CEO Insitute for Policy Advancement	Special Government Employee (SGE) Member
Stocks, Lisa	11/28/2016	11/27/2020	Executive Director, Lifesharing	Representative Member
Uhl, Lynne	11/28/2016	11/27/2019	Director, Division Laboratory and Transfusion Medicine	Representative Member
Verdun, Nicole	09/30/2018	09/30/2020	FDA OBER	Ex Officio Member
Wilton, Frank	11/28/2016	11/27/2019	President and CEO Officer	Representative Member

Number of Committee Members Listed: 31

Narrative Description

The Secretary is responsible under Sections 301, 351, and 361 of the Public Health Service Act, as amended (42 U.S. Code 241, 262, 264), and various provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), for carrying out research in health fields including diseases involving blood and blood products, and for issuing and enforcing regulations concerning the collection, preparation, and distribution of blood and blood products, and regulations related to the transmission of communicable diseases. The Advisory Committee on Blood and Tissue Safety and Availability advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding these broad responsibilities.

What are the most significant program outcomes associated with this committee?

Checked if Applies

- | | |
|---|-------------------------------------|
| Improvements to health or safety | <input checked="" type="checkbox"/> |
| Trust in government | <input checked="" type="checkbox"/> |
| Major policy changes | <input checked="" type="checkbox"/> |
| Advance in scientific research | <input checked="" type="checkbox"/> |
| Effective grant making | <input type="checkbox"/> |
| Improved service delivery | <input checked="" type="checkbox"/> |
| Increased customer satisfaction | <input checked="" type="checkbox"/> |
| Implementation of laws or regulatory requirements | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Outcome Comments

N/A

What are the cost savings associated with this committee?

Checked if Applies

- | | |
|----------------------------|-------------------------------------|
| None | <input type="checkbox"/> |
| Unable to Determine | <input checked="" type="checkbox"/> |
| Under \$100,000 | <input type="checkbox"/> |
| \$100,000 - \$500,000 | <input type="checkbox"/> |
| \$500,001 - \$1,000,000 | <input type="checkbox"/> |
| \$1,000,001 - \$5,000,000 | <input type="checkbox"/> |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/> |
| Over \$10,000,000 | <input type="checkbox"/> |
| Cost Savings Other | <input type="checkbox"/> |

Cost Savings Comments

Improved quality care through increased safety and availability of blood, blood products,

plasma clotting factors, tissue products and transplantation safety is difficult to measure. Many recommendations are made which influence policy and the prevention of disease.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

164

Number of Recommendations Comments

The Committee findings and recommendations detail the widespread, ongoing fiscal crisis within the blood banking industry. No additional recommendations were made during FY18.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

30%

% of Recommendations Fully Implemented Comments

Recommendations made during previous fiscal years are long-term recommendations requiring coordination and collaboration within HHS.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

20%

% of Recommendations Partially Implemented Comments

Many of the recommendations require long-term action which can not be accomplished in a fiscal year. Three subcommittees have been established to work on the recommendations not yet implemented

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

Internally the recommendations are provided to the PHS agencies which support the ACBTSA. These recommendations are discussed, if needed, at the Blood, Organ, and Tissue Senior Executive Council (BOTSEC) as described in the internal charter. Feedback is provided to the ACBTSA through direct communication that the DFO has with the Assistant Secretary for Health. The DFO provides this information initially to the

Committee Chair and then to the Committee at the next scheduled public meeting. The DFO provides the Committee information on the progress and outcome.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input checked="" type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input checked="" type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

The Committee has worked with HHS operating divisions to realign priorities and provide clarification in some areas for transfusion and transplantation safety.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Access Comments

N/A